



THE REGULATOR

FOR THE WELL INFORMED LABORATORY



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IMPORTANT INFORMATION FOR YOU FROM FDA/CDRH

The FDA Center for Devices and Radiological Health {CDRH} has posted a Class I recall notice for **MISYS** Healthcare Systems lab information system software. Versions 5.2, 5.23, and 5.3 of the software have demonstrated a defect that could result in quality assurance information not being included in the patient report. If you have that system and are not aware of the problem, please contact the vendor.

The CDRH has also issued a Class I recall notice for the VIDAS Chlamydia Assay. The recalling firm is bioMérieux in

Durham, N. C. Bovine serum albumin contained in the reagent strip is causing an accelerated degradation of the product's performance and creating the potential for false negative results to be reported. Continued use of the product could result in a moderate or high risk of serious adverse

Adverse health consequences or death. There is a website maintained by FDA for information like these recalls. Jot this address down somewhere and check it every so often.

[Http://www.fda.gov/medwatch/safety/2003/safety03.htm#vidas](http://www.fda.gov/medwatch/safety/2003/safety03.htm#vidas)



Special points of interest:

- ? CATS Dirty Little Secret
- ? Surveyor Profile

Give Yourself A Pat on the Back

It has been a hard year
For labs and laboratorians
Be assured that you are
Appreciated for all you do
On behalf of the citizens
Of Georgia.





BIOTERRORISM

Recommended Biosafety Levels for Infectious agents

BSL	AGENTS	PRACTICES	SAFETY EQUIPMENT (PRIMARY BARRIERS)	FACILITIES (SECONDARY BARRIERS)
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink
2	Human disease, hazard = per-cutaneous injury, ingestion, Mucous membrane exposure	BSL-1 practice plus ? limited access ? Biohazard warning signs ? Sharps Precautions ? Biosafety Manual	Primary Barriers = Class I or II Biosafety Cabinet (BSC) or other physical Containment devices used for all manipulations of Agents that cause splashes or aerosols of infectious materials; personal Protective equipment (PPE) = lab coats, gloves, Face protection as needed.	BSL-1 plus Autoclave available
3	Indigenous or exotic Agents with potential for aerosol transmission; disease May have serious or Lethal consequences.	BSL-2 practice plus: ? controlled access ? decontaminate all waste ? decontaminate all lab clothing before laundering ? Baseline serum	Primary barriers = Class I or II BSC's or other physical containment devices used for all open manipulations of agents; PPE's: protective clothing gloves, respiratory protection as needed.	BSL-3 plus: ? Physical separation from access Corridors ? Self-closing, Double-door access ? Exhausted air not recirculated ? Negative airflow into lab.
4	Dangerous/exotic Agents that pose high risk of life-threatening disease, Aerosol transmitted lab infections, or related agents with unknown risk of transmission.	BSL-3 practice plus: ? clothing change before entering ? Shower before exit ? All material decontaminated on exit from facility	Primary barriers = all procedures conducted in Class III BSC's OR Class I or II BSC's in combination with full-body, air-supplied positive pressure personnel suit	BSL-3 plus: ⌘ Separate building or isolated zone ⌘ Dedicated air supply and exhaust, Vacuum, and decon systems

Surveyors will be asking you for information regarding the biosafety level of the laboratory and other questions regarding your Bioterrorism readiness. Do you have a plan? For more information obtain a

BIOTERRORISM CONTINUED FROM PAGE ONE

Copy of the chart and "Biosafety in Microbiological and Biomedical Laboratories" published by the Centers for Disease Control and Prevention and the National Institutes of Health. You can contact the Government Printing Office at 202-512-1800, fax at 202-512-2250 or you can order on-line at: http://orders.access.gpo.gov/su_docs/sale/prf/prf.html The cost is \$13.50 per copy and the stock number is 017-040-00547-4. It has everything you need to know about biosafety.

ANTI-MICROBIAL SUSCEPTIBILITY TESTING

Anyone interested in updated information about anti-microbial susceptibility testing can order an educational CD-ROM from the Association of Public Health Laboratories free of charge. The address is:

APHL
2025 M Street, NW Suite 550
Washington, D.C. 20036
[Http://www.aphl.org/](http://www.aphl.org/)



ACCEPTABLE PLAN OF CORRECTION 290-9-8-.30 (7)

The Plan must state:

How the deficient practice will be/was corrected;

What corrective action(s) have been taken for patients found to have been affected by the deficient practice;

How the lab has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken;

What measure has been put into place or what systemic changes have been made to ensure the deficiency does not reoccur; and

How the corrective action(s) is being monitored to ensure the deficient practice does not reoccur.



Cat's Christmas Prayer

Now I lay me down to sleep

I pray this cushy life to keep

I pray for toys that look like mice

And sofa cushions, soft and nice.

I pray for gourmet kitty snacks

And someone nice to scratch my back

For window sills all warm and bright

For shadows to explore at night.

I pray I'll always stay real cool

And keep the secret feline rule

To NEVER tell
a human

That

The world is really
Ruled by CATS.



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To all of you who have asked about my health or sent encouraging messages, I sincerely thank you. I am doing well now except the darned old hair isn't growing fast enough. Also You all boosted my spirits. Bless you one and all. Betty Logan Also, Barnes Walker received a heart transplant in September and is doing very well. He has retired but still manages to bug us often. He says to thank everyone for thinking of him.

Protecting Public Health and Safety Through Regulatory Oversight

Proficiency Testing

Please remember that it time to renew proficiency testing enrollment at your facilities for t2004. You must check the box to have results sent to CMS/State. Pay attention to detail when filling out forms. A review of some whole blood glucose results shows alarmingly bad results like 0%, 20%, and 60%. From nursing homes nursing areas in hospitals and clinics. This does not bode well for diabetics. Waived drug screen results are appalling, as well. Even though we don't grade waived testing for drug screens or require PT for state licensure on whole blood glucose, you need to be aware of the results emanating from your facility. Some of it is clerical and some of it is testing error. Please be careful with PT and patient testing.

Meet The DSU Lab staff



Diane Gardner

Diane has been with the Lab Survey Unit since 1987. Prior to state service, she was at Quest and Georgia

Regional Hospital in Atlanta.

Diane has two children of the hairy variety. Her prized possessions are two miniature dachshunds named Mutt and Korky They keep the possums at bay.

She collects Disney Animated Films and has quite a selection of out-of-print movies.

Diane is a Snoopy and Friends collector as well. She is

definitely a pack rat extraordinaire. We have seen her garage!

She does a thorough survey, but if asked sweetly {try whining}, She will provide every assistance at her disposal to you.

Diane will have an-
other birthday come January 15, 2004.

